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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,964	07/08/2003	Hector F. DeLuca	1256-00777	8876
26753	7590	08/25/2006	EXAMINER	
ANDRUS, SCEALES, STARKE & SAWALL, LLP 100 EAST WISCONSIN AVENUE, SUITE 1100 MILWAUKEE, WI 53202			WILLIAMS, LEONARD M	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/614,964	Applicant(s) DELUCA ET AL.	
	Examiner Leonard M. Williams	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to a method of treating psoriasis comprising administering an effective amount of (20S)-1 $\alpha$ -hydroxy-2-methylene-19-nor-vitamin D<sub>3</sub>, classified in class 514, subclass 167.
- II. Claims 7-11, drawn to a method of treating a disease selected from the group consisting of leukemia, colon cancer, breast cancer or prostate cancer comprising administering an effective amount of (20S)-1 $\alpha$ -hydroxy-2-methylene-19-nor-vitamin D<sub>3</sub>, classified in class 514, subclass 167.
- III. Claims 12-16, drawn to a method of treating an autoimmune disease selected from the group consisting of multiple sclerosis, lupis, diabetes, mellitus, host versus graft reaction, and rejection of organ transplants, comprising administering an effective amount of (20S)-1 $\alpha$ -hydroxy-2-methylene-19-nor-vitamin D<sub>3</sub>, classified in class 514, subclass 167.
- IV. Claims 17-21, drawn to a method of treating an inflammatory disease selected from the group consisting of rheumatoid arthritis, asthma, and inflammatory bowel diseases, comprising administering an effective amount of (20S)-1 $\alpha$ -hydroxy-2-methylene-19-nor-vitamin D<sub>3</sub>, classified in class 514, subclass 167.

- V. Claim 22, drawn to (20S)-1 $\alpha$ -hydroxy-2-methylene-19-nor-vitamin D<sub>3</sub>, classified in class 514, subclass 167.
- VI. Claims 23-28, drawn to a method of treating a skin condition selected from the group consisting of wrinkles, lack of adequate skin firmness, lack of adequate dermal hydration and insufficient sebum secretion which comprises administering an effective amount of (20S)-1 $\alpha$ -hydroxy-2-methylene-19-nor-vitamin D<sub>3</sub>, classified in class 514, subclass 167.
- VII. Claims 29-38, drawn to a method of treating a metabolic bone disease where it is desired to maintain or increase bone mass comprising administering an effective amount of (20S)-1 $\alpha$ -hydroxy-2-methylene-19-nor-vitamin D<sub>3</sub>, classified in class 514, subclass 167.
- VIII. Claim 39, drawn to a compound having the formula, classified in class 514, subclass 167.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV and VI-VII are directed to related methods of treating by administration of (20S)-1 $\alpha$ -hydroxy-2-methylene-19-nor-vitamin D<sub>3</sub>. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Invention I is drawn to a method treating psoriasis; II is drawn to a method of treating a disease selected from the group consisting of leukemia, colon cancer,

breast cancer or prostate cancer; III is drawn to a method of treating an autoimmune disease selected from the group consisting of multiple sclerosis, lupis, diabetes, mellitus, host versus graft reaction, and rejection of organ transplants; IV is drawn to a method of treating an inflammatory disease selected from the group consisting of rheumatoid arthritis, asthma, and inflammatory bowel diseases; VI is drawn to a method of treating a skin condition selected from the group consisting of wrinkles, lack of adequate skin firmness, lack of adequate dermal hydration and insufficient sebum secretion and VII is drawn to a method of treating a metabolic bone disease where it is desired to maintain or increase bone mass. These conditions are unrelated in etiology and treatment methods and/or targets of action. Psoriasis is often treated with glucocorticosteroids unrelated to vitamin D compounds, rheumatoid arthritis is treated with anti-TNF $\alpha$  compounds such as antibodies, cancer is treated by a wide variety of compounds, skin conditions are treated by a variety of compounds including  $\alpha$ -hydroxy acids, oils, and others. A search of all the listed methods of treatment using the compound as claimed would be broad and not co-extensive for the reasons cited above.

Inventions V and I-IV, VI-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the conditions are unrelated in etiology, treatment methods and/or targets of action. Psoriasis is often treated with glucocorticosteroids, rheumatoid arthritis has been treated

with anti-TNF $\alpha$  antibodies, cancer has been treated by a wide variety of compounds (5-fluorouracil, bleomycin, paclitaxel, etc.), skin conditions are treated by a variety of compounds including  $\alpha$ -hydroxy acids, hydrating oils, and others. Thus the methods can be practiced by a number of compounds all structurally and functionally unrelated to the vitamin D3 compound as claimed.

Inventions VIII and I-IV, VI-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have no direct connection as claimed. VIII is drawn to a compound that is not a vitamin D3 compound as claimed and thus is not contemplated for use in any of the claimed methods.

Inventions VIII and V are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as an intermediate for the synthesis of a variety of vitamin D compounds other than the vitamin D3 compound as claimed, further there are many drug-like compounds that utilize a 6,5-dual ring structure that are unrelated to vitamin D (estrogen, steroid mimics) and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was not made to request an oral election to the above restriction requirement due to the complexity of the restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised



that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**


Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER